

**Department of State Health Services**  
**Agenda Item for State Health Services Council**  
**January 12-13, 2006**

**Agenda Item Title:** Amend 25 TAC §§229.211-229.222 and new §229.210, Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding Human Food

**Agenda Number:** 3f

**Recommended Council Action:**

☐ For Discussion Only

☒ For Discussion and Action by the Council

**Background:** The Policy Standards and Quality Assurance, Foods Group regulates the manufacture and distribution of food in the State. The new section and amendments are necessary to update current good manufacturing and good warehousing practices in manufacturing, packing, or holding human food in regards food safety during manufacturing and storage and distribution.

**Summary:** The rules are being reviewed in accordance with Government Code §2001.039, the state agency four-year review of rules. These rules concern the manufacture, storage and distribution of food throughout the State. The amendments provide for revisions regarding the manufacture and distribution of food.

**Summary of Stakeholder Input to Date (including advisory committees):** The Texas Food Processor's Association was contacted by email.

**Proposed Motion:** Motion to recommend to HHSC approval for publication of rules contained in agenda item # 3f.

**Agenda Item Approved by:** Richard B. Bays /s/

**Presented by:** Julie Loera **Title:** Manager

**Program/Division:** PSQA Foods Group **Contact Name/Phone:** 512-834-6670

**Date Submitted**

12-6-05

## Title 25. HEALTH SERVICES

### Part 1. DEPARTMENT OF STATE HEALTH SERVICES

#### Chapter 229. Food and Drug

#### Subchapter N. Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding Human Food

#### New §229.210

#### Amendments §§229.211 - 229.222

### Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes new §229.210 and amendments to §§229.211 - 229.222, concerning current good manufacturing and good warehousing practice in manufacturing, packing, or holding human food.

### BACKGROUND AND PURPOSE

The new section and amendments are necessary to update current good manufacturing and good warehousing practice in manufacturing, packing, or holding human food in regards food safety during manufacturing and storage and distribution.

Government Code, §2001.039, requires that each state agency review and consider for readoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 229.211 - 229.222 have been reviewed and the department has determined the reasons for adopting the sections continue to exist because rules on this subject are needed.

### SECTION-BY-SECTION SUMMARY

A new §229.210, General Provisions, is added to provide clarification on the facilities subject to this subchapter. Amendments to §229.211 include the addition of new definitions. An amendment to §229.212 clarifies the reference of the U.S. Code of Federal Regulations. Section 229.213 is amended to reference employee health. Section 229.214 is amended to clarify what firms are exempt from these rules. Sections 229.215 and 229.220 reflect grammatical revisions. Section 229.216 is amended to clarify language on pest activity, and to include specific language on approved pesticides. Section 229.217 is amended in several subsections to reflect grammatical revisions, suitable water temperature for hand-washing facilities, and clarification on waste and food waste operations. Section 229.218 is amended to provide clarification on the maintenance of instruments. Section 229.219 is amended in several subsections to include a reference for approved source, update the current cold holding temperature requirements for potentially hazardous foods, and to reflect extensive new language on reduced oxygen packaging. Section 229.221 is amended to add language on approved source, to clarify language on pest activity, and to update the current cold holding temperature for potentially hazardous foods. Section 229.222 is amended to clarify enforcement action on emergency orders and penalties.

### FISCAL NOTE

Julie W. Loera, Manager, Foods Group, has determined that for each calendar year of the first

five years the sections are in effect, there will be no fiscal implications to state or local governments as a result of enforcing or administering the sections as proposed.

#### SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Loera has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed. These entities will not be required to alter their business practices in order to comply with the sections as proposed. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

#### PUBLIC BENEFIT

In addition, Ms. Loera has also determined that for each of the first five years the sections are in effect, the public will benefit from the adoption of the sections. The public health benefits anticipated as a result of enforcing or administering the sections will be a safe food supply from manufacturers and distributors.

#### REGULATORY ANALYSIS

The department has determined that this proposal is not a “major environmental rule” as defined by Governmental Code, §2001.0225. “Major environmental rule” is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

#### TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed rules do not restrict or limit an owner’s rights to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

#### PUBLIC COMMENT

Comments on the proposal may be submitted to Julie W. Loera., Manager, Foods Group, Texas Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, 512-834-6670 or by email to Julie.Loera@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

#### LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Cathy Campbell, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

**STATUTORY AUTHORITY**

The proposed new section and amendments are authorized by the Health and Safety Code, §431.241, which provides the department with the authority to adopt necessary regulations pursuant to the enforcement of Chapter 431; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed new section and amendments affect the Health and Safety Code, Chapters 431 and 1001; and Government Code, Chapter 531; and implements Government Code §2001.039.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

**[Bold Print and Brackets]** = Current language proposed for deletion

Regular Print = Current language

(No Change.) = No changes are being considered for the designated subdivision

§229.210. General Provisions. This subchapter applies to every person engaged in food manufacturing and/or wholesale food distribution regardless of the license or permit held under §§229.181 - 229.184, 229.370 - 229.374, and 229.541 - 229.554 of this chapter, or if the person is exempt from licensure. Retail food establishments, such as grocery stores and restaurants that are located outside the jurisdiction of a local health authority, must also comply with the requirements of §§229.161 - 229.171 and 229.173 - 229.175 of this chapter (Texas Food Establishment Rules) except for the manufacture or wholesale of food as defined by the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code, §§431.221(2) and 431.221(3). Retail establishments that are located within the jurisdiction of a local health authority that permits and inspects retail food establishments and that are required to license as a food manufacturer under §§229.181 - 229.184 of this chapter, must also comply with the applicable rules enforced by the local health authority.

§229.211. Definitions. The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise. Those definitions and interpretations of terms of the Texas Food, Drug, and Cosmetic Act, Texas Health and Safety Code, Chapter 431 **[Federal Food, Drug, and Cosmetic Act (the Act), §201]**, are also applicable when used in this subchapter.

(1) (No change.)

(2) Act – Texas **[Federal]** Food, Drug, and Cosmetic Act, Health and Safety Code, Chapter 431.

(3) - (14) (No change.)

(15) pH -- (Potential of Hydrogen) A measure of the degree of the acidity or the alkalinity of a solution.

(16) Processing – Including, but not limited, to the preparing, blending, filtering, preserving, treating, changing into different market forms, manufacturing, packing, repacking, or labeling of food ingredients and or products.

(17) [(15)] Quality control operation -- A planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the Act.

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(18) [(16)] Raw agricultural commodity -- Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(19) Reduced oxygen packaging -- The reduction of the amount of oxygen in a package by mechanically evacuating the oxygen; displacing the oxygen with another gas or combination of gases; or otherwise controlling the oxygen content in a package to a level below that normally found in the surrounding atmosphere, which is 21% oxygen. The term includes methods that may be referred to as altered atmosphere, modified atmosphere, controlled atmosphere, low oxygen, and/or vacuum packing including sous vide.

(20) [(17)] Rework -- Clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

(21) [(18)] Safe-moisture level -- A level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity ( $a_w$ ). An ( $a_w$ ) will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given ( $a_w$ ) will not support the growth of undesirable microorganisms.

(22) [(19)] Sanitization -- The application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, yield a reduction of 5 logs, which is equal to a 99.999% reduction of representative disease microorganisms of public health importance.

(23) [(20)] Shall -- Term to state mandatory requirements.

(24) [(21)] Should -- Term to state recommended or advisory procedures or identify recommended equipment.

(25) [(22)] Water activity ( $a_w$ ) -- A measure of the free moisture in a food. The quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§229.212. Current Good Manufacturing Practice.

(a) (No change.)

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(b) Food subject to the requirements of these sections may also be subject to specific regulations **[current good manufacturing practice regulation]** found in Title 21, Code of Federal Regulations (CFR), or in other sections of this title (25 Texas Administrative Code).

§229.213. Personnel. The plant management shall take all reasonable measures and precautions to ensure the following:

(1) Disease control and employee health. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness; open lesion, including boils, sores, or infected wounds; or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.

(2) - (4) (No change.)

§229.214. Exclusions. The following operations are not subject to this section: Establishments engaged solely in the harvesting, storage, or distribution of one or more raw agricultural commodities which are ordinarily cleaned and packed **[cleaned, prepared, treated, or otherwise processed]** before being marketed to the consuming public.

§229.215. Plant and Grounds.

(a) (No change.)

(b) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:

(1) provide sufficient space for the **[such]** placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food;

(2) - (7) (No change.)

§229.216. Sanitary Operations.

(a) - (c) (No change.)

(d) Pest control.

**§§229.216 - 229.217**

(1) No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. This exclusion of pests includes:

(A) no evidence of pest activity in non-food areas;

(B) no evidence of pest activity in food storage or food preparation areas;

and

(C) no evidence of pest activity in or on food products, food packaging or food preparation utensils, equipment, or devices.

(2) Only pesticides approved by the Environmental Protection Agency (EPA) for use in a food processing facility may be used. Pesticides shall be used only according to label directions. Rodenticides shall be placed inside enclosed bait boxes or other approved receptacles. Only a licensed pesticide applicator may apply restricted use pesticides.

(3) The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

(e) - (f) (No change.)

§229.217. Sanitary Facilities and Controls. Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

(1) Water supply. The water supply shall be sufficient for the operations intended and shall be derived from an approved source.

(A) Requirements for approved source. Sources in Texas shall comply with the following requirements.

(i) Public water systems. Sources in Texas which are public water systems shall comply with the Texas Health and Safety Code, Chapter 341, Subchapter C, concerning drinking water standards and rules adopted **[thereunder]** by the Texas Commission on Environmental Quality [Texas Natural Resource Conservation Commission], 30 Texas Administrative Code (TAC), §§290.101 - 290.122 (relating to Drinking Water Standards Governing Drinking Water Quality and Reporting Requirements for Public Water Supply Systems), and §§290.38 - 290.47 (relating to Rules and Regulations for Public Water Systems).



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(ii) - (iii) (No change.)

(B) (No change.)

(C) Any water that is used for hand washing or contacts food or food-contact surfaces shall be safe and of sanitary quality for its intended use. Hot and cold running [Running] water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities. Hot water generation and distribution systems shall be sufficient to meet peak hot water demands throughout the facility.

(2) - (4) (No change.)

(5) Hand-washing facilities. Hand-washing facilities shall be adequate in number and location and be furnished with: **[running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:]**

(A) running water at a temperature of at least 110 degrees Fahrenheit;

(B) a supply of hand cleaning liquid, powder, or bar soap; and

(C) individual disposable towels, continuous towel system that supplies a user with a clean towel, or a heated-air hand drying device.

**[(A) hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands;]**

**[(B) effective hand-cleaning and sanitizing preparations;]**

**[(C) sanitary towel service or suitable drying devices;]**

**[(D) devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands;]**

**[(E) readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, or food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces; and]**

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**[(F) refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.]**

(6) Waste **[Rubbish and offal disposal]**. Waste **[Rubbish and any offal]** shall be so conveyed, stored, and disposed of as to minimize the development of odor; minimize the potential for the waste becoming an attractant and harborage or breeding place for pests; and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces, except as allowed in §229.217(7).

(7) Food waste. Bread, nonmeat pastry products, and produce that have been completely removed from all packaging may be disposed of by alternate means according to any applicable requirements of Title 30, Texas Administrative Code (TAC), Chapters 330, 332, and 335, or Title 4, TAC, Chapter 55.

§229.218. Equipment and Utensils.

(a) - (e) (No change.)

(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and in sufficient quantity for their designated uses. The instruments shall be operated, maintained, and calibrated according to the manufacturer's directions. **[and properly maintained, and in sufficient quantity for their designated uses.]**

(g) (No change.)

§229.219. Production and Process Controls. All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with good public health and sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Testing procedures shall be used where necessary to identify sanitation failures or possible food contamination by chemicals, microbes, or extraneous materials. All food that has become contaminated to the extent that it is adulterated within the meaning of the Act shall be rejected, or if permissible, treated or processed to eliminate the contamination.

(1) Raw materials and other ingredients.

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(A) Food including raw ingredients and finished product shall be obtained from an approved source.

(B) [(A)] Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of sanitary quality for its intended use. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to contamination or deterioration of food.

(C) [(B)] Raw materials and other ingredients shall either: not contain levels of microorganisms that may produce food poisoning or other disease in humans; or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the Act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.

(D) [(C)] Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.

(E) [(D)] Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

(F) [(E)] Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at a temperature and relative humidity and in a manner to prevent the food from becoming adulterated within the meaning of the Act. Material scheduled for rework shall be identified as such.

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**(G) [(F)]** Frozen raw materials and other frozen ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the Act.

**(H) [(G)]** Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

(2) Manufacturing operations.

(A) - (B) (No change.)

**(C) The internal temperature of potentially hazardous foods during transport and storage shall be maintained at or below 41 degrees Fahrenheit as appropriate for the food using methods, that include refrigeration, pre-chilled insulated coolers, dry ice, or storage on ice made from potable water. The method used must maintain the required temperature for the entire length of time the food is in transport or storage. [The internal temperature of potentially hazardous foods during transport and storage shall be maintained at 45 degrees Fahrenheit or lower as appropriate for the food.]**

**[(i) After October 5, 2003, the internal temperature of potentially hazardous foods shall be maintained at 41 degrees Fahrenheit or lower as appropriate for the food.]**

**(i) [(ii)]** Frozen foods shall be kept frozen at all times.

**(ii) [(iii)]** Shell eggs, after initial packing, must be transported and stored at a temperature of 45 degrees Fahrenheit or less. If the United States Department of Agriculture and the U.S. Food and Drug Administration determine by law that a lower temperature must be maintained, the lower temperature shall prevail.

**(iii) [(iv)]** The temperature of molluscan shellfish **[shellstock]** from the harvester through the original shellfish dealer shall be maintained in accordance with §§241.58 - 241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellfish **[shellstock]** shall be adequately iced or refrigerated at 45 degrees Fahrenheit or less during all subsequent distribution, storage, processing, and sale.

**(iv) [(v)]** Hot foods shall be maintained at 135 **[140]** degrees Fahrenheit (60 degrees Celsius) or above.

(v) [(vi)] Acid or acidified foods shall be heat treated to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

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(D) - (O) (No change.)

(P) Reduced oxygen packaging. Manufacturers performing reduced oxygen packaging:

(i) shall maintain Standard Operating Procedures (SOPs) that:

(I) limit the shelf life of foods to not more than 14 calendar days from the date the food is packaged to the date the food is consumed or the original manufacturer's "sell by" or "use by" date, whichever comes first, except as described in clause (vi) of this subparagraph;

(II) Describe how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:

(-a-) "use by" and provide a date that is within 14 calendar days of packaging or provide a date as allowed by clause (v) of this subparagraph; and

(-b-) keep the food refrigerated at 41 degrees Fahrenheit or below;

(III) require employees that contact foods with bare hands to wash hands properly or utilize proper utensils;

(IV) designate raw food and ready to eat food areas and place physical barriers or effective methods that minimize the risk of cross-contamination between raw foods and ready-to-eat foods and restrict access to the food processing equipment to personnel who are trained to operate the equipment and understand the risks of cross-contamination;

(V) describe cleaning and sanitization procedures for food-contact surfaces; and

(VI) describe the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:

(-a-) concepts required for safe operation;

(-b-) equipment and facility; and

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(vii) of this subparagraph:

(ii) shall maintain records that document employee training. Records documenting training must be maintained for at least one year after the employee leaves the company or is moved to other duties that do not include vacuum packaging. The records must be available at the packaging facility or corporate offices for review by the regulatory authority;

(iii) shall maintain food processing records for at least one year from the time the food is packed. The records must be available at the facility or corporate offices for review by the regulatory authority. The records must contain the following information:

(I) the identity of the food that is packaged;

(II) the date the food was packaged; and

(III) the name of the operator performing the food packaging; and

(iv) shall limit the types of foods that are packaged to a food that does not support the growth of *Clostridium botulinum* because it complies with one of the following:

(I) has a water activity ( $a_w$ ) of 0.91 or less;

(II) has a hydrogen ion concentration (pH) of 4.6 or less;

(III) is a meat or poultry product cured at a food processing plant regulated by the U.S. Department of Agriculture or the department, and is received in an intact package; or

(IV) is a food with a high level of competing organisms such as raw meat or poultry.

(v) food products, other than those specified in clause (iv) of this subparagraph may be vacuum packaged if the firm provides written documentation of product

testing such as shelf life studies of the product under the same storage and packaging conditions or scientific studies of the product which must be the same species, market form, packaging, and holding conditions that prove the reduced oxygen packaged product will not support the growth of *Clostridium botulinum*;

(vi) the shelf life of a vacuum packaged product may be extended past the 14 day shelf life limit as specified in clause (i)(I) of this subparagraph if the firm provides written documentation of product testing such as shelf life studies of the product

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under the same storage and packaging conditions or scientific studies of the product which must be the same species, market form, packaging, and holding conditions that prove the extended shelf life of the reduced oxygen packaged product will not support the growth of *Clostridium botulinum*, *Listeria* and *Salmonella*;

(vii) fish shall not be packaged in reduced oxygen packaging unless the fish is frozen before, during, and after packaging unless the firm is subject to §§229.121 - 229.129 of this title (relating to Seafood HACCP).

(Q) [(P)] Unshelled pecans shall be thoroughly cleaned to remove foreign matter before cracking. After cleaning, unshelled pecans shall be sanitized.

(R) [(Q)] When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.

(S) [(R)] Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

§229.220. Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazard.

(a) - (c) (No change.)

(d) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Department of State Health Services [Texas Department of Health, Manufactured Foods Division], 1100 West 49th Street, Austin, Texas, 78756.

§229.221. Good Warehousing Practice.

(a) - (b) ( No change.)

(c) Sanitary operations.

(1) (No change.)

(2) Food storage facilities and transportation vehicles shall be kept free of rodents, insects, birds, and other pests which may contaminate food which includes:[.]

(A) no evidence of pest activity in non-food areas;

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(B) no evidence of pest activity in food storage areas; and

(C) no evidence of pest activity in or on food products, food packaging or food preparation utensils, equipment or devices.

(3) (No change.)

(4) The internal temperature of potentially hazardous foods during transport and storage shall be maintained at or below 41 degrees Fahrenheit as appropriate for the food using methods that include refrigeration, pre-chilled insulated coolers, dry ice, or storage on ice made from potable water. The method used must maintain the required temperature for the entire length of time the food is in transport or storage. [The internal temperature of potentially hazardous foods during transport and storage shall be maintained at 45 degrees Fahrenheit or lower as appropriate for the food.]

[(A) After October 5, 2003, the internal temperature of potentially hazardous foods shall be maintained at 41 degrees Fahrenheit or lower as appropriate for the food.]

(A) [(B)] Frozen foods shall be kept frozen at all times.

(B) [(C)] Shell eggs after initial packing, must be transported and stored at a temperature of 45 degrees Fahrenheit or less. If the United States Department of Agriculture and the U.S. Food and Drug Administration determine by law that a lower temperature must be maintained, the lower temperature shall prevail.

(C) [(D)] The temperature of molluscan shellfish **[shellstock]** from the harvester through the original shellfish dealer shall be maintained in accordance with §§241.58 - 241.60 of this title (relating to Molluscan Shellfish). Raw molluscan shellfish **[shellstock]** shall



be adequately iced or refrigerated at 45 degrees Fahrenheit or less during all subsequent distribution, storage, processing, and sale.

(5) - (11) (No change.)

(d) Other provisions.

(1) Distressed foods salvaged by the licensee shall be salvaged in accordance with §§229.541-229.554, 229.571-229.584, 229.601-229.614, and 229.631-229.647 **[[§§229.191 - 229.202]** of this title (relating to Regulation of Food, Drug, Device, and Cosmetic Salvage Establishments and Brokers).

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(2) - (3) (No change.)

(e) Food including raw ingredients and finished food products shall be obtained from an approved source.

§229.222. Enforcement. **[Penalties.]**

(a) - (b) (No change.)

(c) Administrative penalties as provided in Health and Safety Code §431.054, §431.055, §431.056, §431.057, §431.058, and in §229.261 of this title (relating to Assessment of Administrative **[or Civil]** Penalties), may be assessed for violation of these sections. If the person charged with the violation does not request a hearing, the Commissioner of the Department of State Health Services (Commissioner) or the Commissioner's designee may assess a penalty after determining that a violation has occurred and the amount of the penalty.

(d) Emergency orders as provided in Health and Safety Code §431.045 may be issued by the Commissioner or the Commissioner's designee.

Agency Unit/Section/Division Policy, Standards and Quality Assurance – Foods Group	Council Meeting Date November 2005
Agency Program Contact Bill Willis	Telephone No. 512-834-6670
Rule Topic 25 TAC §§229.211-229.222 Current Good Manufacturing and Good Warehousing Practice in Manufacturing, Packing, or Holding Human Food	

### 1. Rule Summary.

(Briefly summarize the rule change and why the rule may or may not have fiscal implications.)

This rule will be presented as a proposed rule at the January 2006 meeting of the DSHS Advisory Council. Pursuant to the Government Code, §2001.39, each state agency is required to review and consider for re-adoption each rule adopted by that agency. The current rules have been reviewed and the department has determined that reasons for adopting the sections continue to exist. Several changes were made to all sections of 25 TAC §§229.211-229.222. These changes ranged from minor grammatical changes to major additions of new language and terminology. This rule has no impact on local government.

### 2. Fiscal Impact.

Does the rule have foreseeable fiscal implications to either costs or revenues of state government for the first five years the rule is in effect?

☐ Yes ☒ No If yes, complete the following:

- (a) If there are estimated additional costs to the department, explain (1) what new responsibilities will be required; (2) what additional staff will be needed (numbers and classifications); and (3) what other expenses, such as capital or professional services, will be required. Explain any key assumptions that will be needed to reach the figures in the chart in 2(d).

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- (b) If there is an estimated reduction in costs, explain how the reductions will be accomplished.

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- (c) If there is an estimated increase in revenue, describe the source and amount. If there is an estimated loss of revenue, describe the source and amount.

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**Note:** Staff may provide the information in (d) on a separate spreadsheet. If spreadsheet is attached, please check here: ☐

(d)	1. Fiscal Year 2006	2. Fiscal Year 2007	3. Fiscal Year 2008__	4. Fiscal Year 2009__	5. Fiscal Year 2010
Estimated Additional/Reduction in Cost (specify reduction in parenthesis)					
STATE FUNDS					
FEDERAL FUNDS					
OTHER FUNDS					
<b>TOTAL:</b>					
Estimated Increase/Loss of Revenue (specify loss in parenthesis)					

Health and Human  
Services  
Enterprise

**Attachment 4**

**Rulemaking Fiscal Impact**

June 2005

STATE FUNDS					
FEDERAL FUNDS					
OTHER FUNDS					
<b>TOTAL:</b>					

**3. Local Government Impact.**

Does the rule have foreseeable positive or negative fiscal implications to either costs or revenues of local governments for the first five years the rule is in effect?

☐ Yes ☒ No If yes, enter the amounts for each of the five years and explain key assumptions you used to reach the figures.

**4. Small Businesses or Micro-Businesses Impact.**

Does the rule have ANY adverse economic effect on small businesses or micro-businesses\* (regardless of whether it will have an adverse effect on businesses in general)?

☐ Yes ☒ No If yes, complete 4B–E. If no, complete 4A.

\* A small business is a legal entity, including a corporation, partnership, or sole proprietorship, that is formed for the purpose of making a profit, is independently owned and operated, and has fewer than 100 employees OR less than \$1,000,000 in annual gross receipts.

A micro-business is a legal entity, including a corporation, partnership, or sole proprietorship, that is formed for the purpose of making a profit, is independently owned and operated, and has 20 or fewer employees.

A. If the rule **will not** have an adverse economic effect on either small businesses or micro-businesses, or both, explain why there will be no adverse effect on one or both.

These amendments provide updates and allow the rule to be consistent with other current regulations written by the department. The amendments also comply with Government Code 2001.039.

**Complete (B)-(E) if rule will have an adverse economic effect on small businesses or micro-businesses or both.**

**Note:** You must discuss both small businesses and micro-businesses in your analysis regardless of whether the rule will have an adverse economic effect on either one or both.

B. Explain why there will be an adverse economic effect, such as new fees, reduced revenues, or new regulatory requirements that will increase the cost of doing business.

C. Give an analysis of the cost to small businesses or micro-businesses of complying with the rule. Explain what assumptions you used to calculate these projected costs (for example, a survey of randomly selected assisted living facilities).

D. Compare the cost to small businesses or micro-businesses of complying with the rule with the cost to the largest businesses affected by the rule, analyzing, when possible:

- cost per employee,
- cost per hour of labor, or
- cost per each \$100 of sales.

- E. Give an analysis of whether it is legal and feasible to reduce the economic effect of the rule on small businesses or micro-businesses, while still accomplishing the intent of the state or federal law being implemented with the rule.

**5. Other Cost Impacts.**

If there will be costs to persons who must comply with this rule change, other than costs identified in preceding sections, enter estimated costs for the first five fiscal years of implementation:

FY 1	FY 2	FY 3	FY 4	FY 5

Explain assumptions used to arrive at these costs.

N/A

**6. Fiscal Impact on Local Employment:**



Rule **will not** have an impact.



Rule **will** have an impact. You must complete an Economic Impact Request and submit it to TWC at least 30 days before the Council meeting.

**7. Takings Impact Assessment.**

Does the proposed rule create a burden on private “real property” (i.e. real estate or the buildings and other structures attached to real estate)?



**Yes**



**No**

If **yes**, contact Legal **immediately** to determine if you are required to complete a Takings Impact Assessment.

**Approvals**

Signature – Budget Analyst (original signature on file)	Date	Telephone No.
Signature – Budget Director (original signature on file)	Date	Telephone No.
Signature – Chief Financial Officer (original signature on file)	Date	Telephone No.
Signature – Deputy Executive Commissioner (as appropriate) (original signature on file)	Date	Telephone No.